South Carolina Department of Labor, Licensing and Regulation
South Carolina Board of Pharmacy
110 Centerview Dr. • Columbia • SC • 29210
P.O. Box 11927 • Columbia • SC 29211-1927
Phone: 803-896-4700 • Contact.pharmacy@llr.sc.gov • Fax: 803-896-4596
llr.sc.gov/bop

NON-RESIDENT MANUFACTURER/REPACKAGER PERMIT APPLICATION REQUIREMENTS AND INSTRUCTIONS

A Manufacturer/Repackager Permit is required for a facility to engage in the manufacturing of prescription drugs or devices, including any packaging or repackaging of the drugs and/or devices, and/or labeling or re-labeling of containers. A South Carolina Manufacturer/Repackager Permit Application has a one-year expiration. A Manufacturer/Repackager Permit is required for Virtual Manufacturers or any company that sells their own prescription drug products and/or medical devices but outsources the manufacturing and distribution operations.

If you are also distributing your own products, you will need to concurrently apply for a wholesale distributor permit.

If you are using a 3PL or another wholesale distributor to distribute your products into South Carolina, they must be permitted in South Carolina.

Regulations 99-43(G)(3)(b) requires the permit holder to appear before the Non-Resident Application Review Committee to answer questions about all aspects of the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection. **All requested information and emailed confirmation are required prior to the meeting date.**

Failure to complete all required fields and/or provide necessary supplemental documentation will delay the application process. If an item is not applicable, please indicate N/A. **In order to avoid delay, please do not provide the items below in a binder, folder or use dividers. Also, provide items in the order as listed below. Only use one side of paper. Please write legibly. Retain copies of all documents submitted.**

Include this checklist with your application (check N/A if not applicable):

Included	N/A	
☐	☐	Check or money order only (no cash) in the amount of $700 made payable to SC Board of Pharmacy. (Application fee is non-refundable. A returned check fee of up to $30, or an amount specified by law, may be assessed on all returned funds.)
☐	☐	Copy of all operational inspection reports conducted within the last two years.
☐	☐	Copy of FDA inspection, any 483(s) issued, and applicant's response
☐	☐	Copy of FDA registration
☐	☐	Copy of current DEA registration
☐	☐	Copy of state controlled substance registration
☐	☐	Copy of policy and procedure for shipping refrigerated products and monitoring temperature and humidity
☐	☐	Copy of policy and procedure on security, disaster plans and recordkeeping
☐	☐	Copy of licensure from resident state
☐	☐	A letter describing, in detail, the nature of your business
☐	☐	Provide a list of all pharmacy permits/licenses and license numbers held in other states
☐	☐	Photographs of: o Entrance o Exit o Product Area
☐	☐	Organizational chart from the ultimate parent company down to and including the Applicant
☐	☐	If a change of ownership, include organization charts of before and after the change. Chart must include names of owners with a 10% or greater ownership interest if a non-publicly traded company.

If you are a virtual manufacturer, also include the items below:

Included	N/A	
☐	☐	Provide the name, address, and South Carolina permit number of all 3PLs and/or wholesale distributors you will be using. If available, provide the Drug Distributor accreditation certificate or a notarized letter certifying these facilities are in compliance with NABP standards.
☐	☐	Provide a list of the names and addresses of all contract manufacturers and verification of FDA registration for each.
☐	☐	Provide a policy and procedure confirming the facility's business responsibilities of oversight of the contract manufacturer and 3PLs, including appropriate manufacturing and storage conditions.
☐	☐	Provide a list of current officers, directors and/or managers summarizing their qualifications and describing their duties.
☐	☐	Provide an attestation that this facility does not hold products and does not contract with Manufacturers to distribute drugs/devices other than these for which it owns the NDA, ANDA or UDI numbers.

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NON-RESIDENT MANUFACTURER/REPACKAGER PERMIT APPLICATION

☐ New Facility

☐ Change to Existing Permit (Permit No.: _____)
- ☐ Change of Name
- ☐ Change of Location (from one city to another)
- ☐ Change of Ownership (include organizational chart before and after change)

For Board Use Only	
Date Paid	
Amount Paid	
Check No.	

Type of Activity (check all that apply):
☐ Manufacturer ☐ Packager/Repackager ☐ Virtual Manufacturer ☐ Labeler/Relabeler

FACILITY INFORMATION

Federal Tax ID No.: _____ NABP e-Profile ID No.: _____ Resident State License No.: _____

Legal Facility Name: _____

DBA Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

Is application based on a change in ownership? ☐ Yes ☐ No

If Yes: _____ SC Permit No.: _____
Previous Name of Facility

Name of Designated Representative: _____ Phone No.: _____

Email for Designated Representative: _____

Mailing address where all correspondence regarding licensure will be mailed if other than facility above:

Contact Person: _____ Email: _____

Facility Name: _____

Mailing Address: _____ City: _____ State: ___ Zip: _____

1. Has your facility been inspected by the FDA? ☐ Yes ☐ No
2. If inspected by the FDA, was your facility issued a 483? ☐ Yes ☐ No
   If Yes, provide a copy of the FDA Form 483 and your company's response to the issues noted.
3. Are you currently shipping into South Carolina from this facility? ☐ Yes ☐ No
   If Yes, provide a list of customers.
4. Which of the following entities do you sell/ship product to? Check all that apply:
   ☐ Pharmacies ☐ Hospitals ☐ Clinics/Surgical Centers ☐ Wholesalers
   ☐ Dentists ☐ Physicians ☐ Podiatrists ☐ Government Agencies
   ☐ Nursing Homes ☐ Veterinarians ☐ Optometrists
   ☐ Other (specify): _____

5. Will the facility utilize a 3PL or wholesaler to distribute the product? ☐ Yes ☐ No

If yes, list all names and locations of distributors (attach additional sheets if necessary):

6. Do you manufacture, repackage, relabel or distribute controlled substances? ☐ Yes ☐ No

If yes, contact SCDHEC Bureau of Drug Control via website at:
www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/

LOCATION OF FACILITY/FACILITIES

Customers in South Carolina to which drugs or devices will be shipped (attach additional sheets if necessary).

Facility Name	City	Telephone No.

OWNERSHIP

☐ **Sole Proprietorship** Name of Business Entity: _____

Name	City, State	Birth Year

☐ **General Partnership** ☐ **LLP** Name of Partnership/LLP: _____

Partner Name	City, State	Birth Year	% of Ownership

☐ **Corporation** ☐ **LLC** Legal Name of Corporation/LLC: _____

Is this facility publicly traded? ☐ Yes ☐ No

Name of Parent Company: _____ State of Incorporation: _____

Name of Individual Owners and Principal Officers	Title	City, State	Birth Year	% of Ownership
1.				
2.				
3.				

DISCIPLINARY HISTORY

If you answer "Yes" to any part of this section, provide a detailed explanation on a separate sheet and attach copies of applicable court documentation. Include the city and state where the offense(s) occurred.

TO THE BEST OF YOUR KNOWLEDGE HAS THE APPLICANT, the entity, undersigned permit holder, any person or entity identified in the ownership/management section above, or any entity under common control with the applicant EVER:

1. Had any license or permit held by the applicant, permit holder, or by any owner or corporate officer, ever been disciplined, denied, refused, voluntarily surrendered, agreed to permanently cease operations or revoked for violations of any federal or state pharmacy laws or drug laws regardless of state? ☐ Yes ☐ No

   Is there any pending disciplinary action? ☐ Yes ☐ No

2. Been convicted, fined or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor in South Carolina or any other state, or in a United States court for:

   a. any offense relating to drugs, narcotics, controlled substances or alcohol, whether or not a sentence was imposed? ☐ Yes ☐ No

   b. any offense involving the practice of pharmacy, or relating to acts committed within a pharmacy or drug/device manufacturer setting or incident to pharmacy practice, whether or not a sentence was imposed? ☐ Yes ☐ No

   c. any offense involving fraud, dishonesty or moral turpitude whether or not a sentence was imposed? ☐ Yes ☐ No

3. Had an application for a drug/device distributor permit, pharmacy, or pharmacist license, permit or certificate or a technician license or registration, denied, refused in South Carolina or any other state or country? ☐ Yes ☐ No

4. Had disciplinary action taken against you, or a pharmacy or drug manufacturer facility you owned, or a pharmacy or drug/device distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country? ☐ Yes ☐ No

5. Operated, or allowed the facility to operate without a valid permit? ☐ Yes ☐ No

6. Violated the drugs/device laws, rules, statutes and/or regulations of South Carolina, any other state, the United States, or any other country? ☐ Yes ☐ No

Section §40-43-83 (E), the board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

ATTESTATION

I declare that I have read and approve the foregoing and the statements are true and correct to the best of my knowledge and belief. I will comply with the requirements contained in the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

Permit Holder Signature	Date
Print Name of Permit Holder	Title
Email Address of Permit Holder	Phone Number

PRIVACY NOTICE

South Carolina law requires the agency to collect personal information which is only disseminated as required by law. The South Carolina Freedom of Information Act ensures that the public has a right to access appropriate records and information possessed by a government agency. Therefore, some personal information on your renewal application and other documents on file may be subject to public scrutiny or release. The Department collects and disseminates personal information in compliance with The South Carolina Freedom of Information Act, the South Carolina Family Privacy Protection Act and other applicable privacy laws and regulations. Additionally, the Department shares certain information on the application with other governmental agencies for various governmental purposes, including research and statistical purposes.